K021287

MAY 07 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Tel: (763) 391-9533
FAX: (763) 391-9603

Preeti Jain, Senior Manager, Regulatory/Clinical Affairs

DEVICE NAME

Trillium™ AFFINITY NT CVR with Filter with Trillium BioPassive Surface

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

AFFINITY Cardiotomy Venous Reservoir (K936003)
AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

DESCRIPTION OF DEVICE

The Trillium™ AFFINITY NT CVR with Trillium BioPassive Surface is a hardshell collection reservoir for venous blood and for blood recovered from Cardiotomy suction and ventricular vent devices. The blood recovered by intracardiac suction and ventricular devices enters the reservoir through the top and passes through a filter media. The design of the reservoir is such that if, under normal operating volume of less than 1000ml and if there is no foaming of the recovered blood, there is no blood contact with the open cell polyurethane defoamer. Venous blood also enters through the top of the reservoir and is mixed with the filtered blood. As with the recovered Cardiotomy blood, under normal operating volume of less than 1000ml if there is no foaming of the venous blood entering the reservoir, there is no blood contact with the defoamer.

STATEMENT OF INTENDED USE

The Trillium™ AFFINITY NT CVR with Trillium BoPassive Surface is indicated for use in the extracorporeal perfusion circuit to collect venous and Cardiotomy suctioned blood during cardiopulmonary bypass procedures

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The AFFINITY Cardiotomy/Venous Reservoir is indicated for use in the extracorporeal perfusion circuit to collect venous and Cardiotomy suctioned blood during cardiopulmonary bypass procedures

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the AFFINITY Cardiotomy/Venous Reservoir. The modification to the currently marketed Cardiotomy/Venous Reservoir is to coat the blood contact surfaces with Trillium™.

The Trillium™ AFFINITY NT CVR is being compared to the following marketed devices:

- AFFINITY Cardiotomy Venous Reservoir (K936003)
- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

The Trillium™ AFFINITY NT CVR has the same indications statement and intended uses as the:

- AFFINITY Cardiotomy Venous Reservoir (K936003)

The Trillium™ AFFINITY NT CVR has "no new technological characteristics (e.g., materials and manufacturing processes)" from the currently marketed Cardiotomy/Venous Reservoir. The technological characteristic is solely the coating material of the blood pathway:

- Trillium™

The technological characteristic of the Trillium™ Biopassive Surface is common to other medical devices (hollow fiber oxygenators) currently in commercial distribution as follows:

- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the Trillium™ AFFINITY NT CVR is substantially equivalent to other marketed extracorporeal cardiopulmonary bypass devices.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Trillium™ AFFINITY NT CVR does not significantly affect safety and effectiveness and is substantially equivalent to other commercially distributed extracorporeal cardiopulmonary devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 07 2002

Mr. Preeti Jain
Senior Manager, Regulatory/Clinical Affairs
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Re: K021287
Trade Name: Trillium™ AFFINITY NT Cardiotomy Venous Reservoir
Regulation Number: 21 CFR 840.4400
Regulation Name: Cardiotomy Reservoir
Regulatory Class: II (two)
Product Code: DTN
Dated: April 22, 2002
Received: April 23, 2002

Dear Mr. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

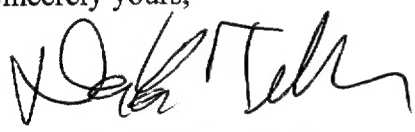
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Trillium™ AFFINITY NT Cardiotomy Venous Reservoir

Indications for Use:

The Trillium™ AFFINITY NT CVR with Trillium BioPassive Surface is indicated for use in the extracorporeal perfusion circuit to collect venous and Cardiotomy suctioned blood during cardiopulmonary bypass procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter use ___
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K031284